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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

KRAMER, NICOLE R

ART UNIT PAPER NUMBER

3762

DATE MAILED: 09/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/089,997

Applicant(s)

HAYES-GILL ET AL.

Examiner

Nicole R. Kramer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18, 24 is/are rejected.
- 7) ☒ Claim(s) 19-23 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 April 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 4/8/02.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,781,200 ("Baker").

Baker discloses an apparatus for detecting the heart rate of a fetus (fetal monitoring system 20), including at least two electrodes positioned on the abdomen of the mother in use for detecting ECG signals (plurality of fetal monitoring sensors 35 may be ECG sensors; see col. 5, lines 1-5), a processor for receiving the signals received

from each detector and determining the heart rate of the fetus (control unit 40; see col. 7, lines 20-35). Baker does not specifically disclose that control unit 40 may also determine the heart rate of the mother. However, Examiner notes that it has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138. The control unit of Baker has the ability to determine the heart rate of the mother, because the maternal ECG is detected and processed in order to obtain the fetal heart rate when the fetal heart sensors 35 are ECG sensors (see col. 8, lines 20-40 or col. 10, lines 55-65).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 3-18, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,781,200 ("Baker") in view of "Lead systems for the abdominal fetal electrocardiogram," A van Oosterom, Clin. Phys. Physiol. Meas., 1989, Vol. 10, Suppl. B, 21-26.

Baker fails to specifically disclose that a common electrode forms one of the electrodes of each detector. "Lead systems for the abdominal fetal electrocardiogram," teaches multiple lead configurations for detecting a fetal ECG. The article describes

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one proposed configuration in which an array of electrodes is placed over the abdomen, unipolar signals are recorded with the common reference being at the lower abdomen (see page 24, fifth full paragraph). It would have been obvious to one having ordinary skill at the time of applicant's invention to form a common electrode for the multiple sensors of Baker as taught by van Oosterom in order to reduce the number of required electrodes.

With respect to claims 4-5 and 7, the control unit 40 of Baker includes a visual display (73) of fetal heart rate and can further display other information such as patient history (see col. 6, lines 57-65). Baker fails to specifically disclose that ECG signals or traces can be displayed on display 73. Examiner takes Official Notice that displaying dynamic ECG traces is well known in the art. It would have been obvious to one having ordinary skill at the time of applicant's invention to modify the system of Baker to include such a display in order to provide an operator with the morphology of the ECG trace that may be utilized to detect further abnormalities.

With respect to claim 6, Baker discloses a signal processor for amplifying and filtering the ECG signals detected by the detectors (see Figures 6A-6C and associated text).

With respect to claims 8, 15, and 17, Baker determines the heart rate of the fetus by suppressing the maternal signal (see col. 8, lines 20-40 or col. 10, lines 55-65), detecting peaks of the remaining fetal signal (via peak value processor 183), and determining the time interval between adjacent beats (see col. 18, lines 35-55).

With respect to claim 9, Examiner notes that it has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138. The control unit of Baker has the ability to monitor the fetal heart rate for a predetermined time period of not less than one hour. In addition, with respect to both claims 9 and 16, it would have been obvious to one having ordinary skill in the art at the time of applicant's invention to aggregate the heart rate over a predetermined time period in order to detect sustained low or high fetal heart rates (i.e., see Baker at col. 7, lines 25-29).

With respect to claim 10, the apparatus is portable (see Figs. 1 and 2).

With respect to claim 11, Baker teaches an ambulatory non-invasive fetal monitoring system, and thus incorporates the monitoring sensors into a belt that fits around the mother. Baker fails to specifically disclose "determining the position of the fetus within the womb" and placing the ECG detector "in accordance with the position of the fetus" because the sensor belt is simply placed around the mother in a predetermined fashion. It would have been obvious to one having ordinary skill at the time of applicant's invention to modify the system of Baker to utilize the monitoring system disclosed in Baker in a different medical environment (such as home care or hospital monitoring) because the signal processing system of Baker provides a reliable fetal heart rate and other pertinent information such as fetal position. In such different medical environments, the sensors of Baker may simply be placed onto the abdomen of the mother rather than incorporating the sensors into a belt. It is well known in the art to

position ECG sensors in accordance with the position of the fetus (i.e., see van Oosterom which explains the problem of recording FECG signals due to the uncertainty of the fetus with respect to the maternal abdomen on page 21). It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to position ECG sensors in accordance with the position of the fetus in order to obtain the strongest and most accurate fetal ECG signals.

Baker also fails to specifically disclose monitoring the ECG signals for a predetermined length of time greater than one hour. It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to monitor the heart rate over a predetermined time period in order to detect sustained low or high fetal heart rates (i.e., see Baker at col. 7, lines 25-29).

With respect to claim 14, Examiner takes Official Notice that palpating the mother abdomen is a well-known method of determining the position of the fetus within the womb. It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to palpate the mother's abdomen to determine the position of the womb in order to position ECG sensors in accordance with the position of the fetus and thus obtain the strongest and most accurate fetal ECG signals.

With respect to claim 18, Examiner takes Official Notice that it is well known in the art to monitor the mother's heart rate in addition to the fetal heart rate (as evidenced by U.S. Patent No. 5,666,959). It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the monitoring system of Baker to

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detect the heart rate of the mother in order to monitor the mother's well being while simultaneously monitoring the fetus's well being.

Allowable Subject Matter

6. Claims 19-23 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

7. The following is a statement of reasons for the indication of allowable subject matter: claims 19-23 relate to determining the fetal heart rate by distinguishing between "erroneous time intervals" and time intervals having a standard deviation lower than a predetermined value. Examiner considers the closest prior art of record to be U.S. Patent No. 6,751,498 ("Greenberg et al."). Greenberg et al. teaches an apparatus for detecting the heart rate of a fetus surface electrodes (10) placed on the mother's abdomen and/or lower back to obtain a "combined waveform" of maternal-plus-fetal waveforms. Greenberg et al. teaches distinguishing between "good" EKG signals and "bad" ECG signals by examining the frequency spectrum of the EKG signal in order to assess the signal integrity of the electrode/sensor. In Greenberg, a signal is considered to be "good" when the spectrum is wide and results in a minimum ration magnitude (see col. 8, lines 38-64). Greenberg et al. is concerned with distinguishing channel integrity rather than distinguishing erroneous time intervals, and thus Examiner considers the subject matter of claims 19-23 to be allowable over the prior art.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

U.S. Patent No. 5,807,271 teaches a plurality of sensors positioned in an array over the mother's abdomen that convert the fetal heart beat sound into an electrical signal. Electrical means compare the signal from different sensors and sends the most valid signal to a monitoring station such that the best signal is provided as the fetus moves positions.

U.S. Patent No. 5,372,139 teaches a method for suppressing a maternal ECG from a fetal ECG which envisions that a plurality of abdominal leads may be placed in order to detect a plurality of composite signals (i.e., see col. 9, lines 35-45).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicole R. Kramer whose telephone number is 571-272-8792. The examiner can normally be reached on Monday through Friday, 8 a.m. to 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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George Manuel